DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 24, 2015

EMcision LTD.
% Mr. Louis-Paul Marin
MMA Certification Incorporated
2025 Michelin
Laval, Quebec H7L 5B7
Canada

Re: K150029
Trade/Device Name: Habib EUS RFA 6700
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI, JOS
Dated: May 21, 2015
Received: May 27, 2015

Dear Mr. Marin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150029

Device Name
Habib EUS RFA 6700

Indications for Use *(Describe)*

The Habib EUS RFA 6700 is indicated for coagulation and ablation of soft tissue when used in conjunction with compatible radio frequency generator.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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EMcision

EMcision Ltd. Habib EUS RFA 6700

510(k) Summary

1.	**Type of submission:**	Traditional
2.	**Preparation Date**	June 22, 2015
3.	**Submitter**	**EMcision Ltd.**
	Address	Department of Surgery Hammersmith Hospital DuCane Road London W12 0HS United Kingdom Phone 1-514-994-9649
	Contact	François Poulin
4.	**Contact Person:**	**Louis-Paul Marin**, ing., LL.B., LL.M. President, MMA Certification Inc.
	Phone:	1-450-781-1578 ext 225
	Fax:	1-450-681-9663
	Email:	lpmarin@groupemma.ca
5.	**Identification of the Device**	
	Proprietary Name/Trade Name	Habib EUS RFA 6700
	Common Name:	Monopolar electrosurgical device
	Classification Name:	Electrosurgical cutting and coagulation device and accessories
	Device Classification:	II
	Regulation Number:	878.4400
	Panel:	79 – General and Plastic Surgery
	Product Code:	GEI, JOS
6.	**Identification of the Predicate**	
	Predicate Device Name:	ACE Monopolar Attachment
	510(k) Number:	K123061
	Predicate Device Name:	LeVeen™Standard Needle Electrode System
	510(k) Number:	K140495

7. Intended use of the subject device

The Habib EUS RFA 6700 is indicated for coagulation and ablation of soft tissue when used in conjunction with compatible radio frequency generator.

8. Device Description

The Habib EUS RFA 6700 is a catheter that is delivered during an EUS procedure, through 19 or 22 Gauge (G) endoscopic needles. The Habib EUS RFA 6700 is monopolar configuration and thus, must be used in conjunction with patient grounding pad. RF energy is produced by connecting the catheter to a compatible RF generator via an accessory cable. When attached to a generator, RF current is emitted from the exposed portion of the electrode and this current translates into ion agitation within the surrounding tissue, which is converted by friction into heat and induces cellular death by mans of coagulation necrosis.

9. Performance Data

Performance bench testing, biocompatibility testing, and electrical testing were performed on the proposed Habib EUS RFA 6700, which demonstrates that it met the required specifications for the completed design verification, biocompatibility tests, and electrical tests.

The following performance bench tests were performed:

- Compatibility with endoscope needle
- Trackability and pushability test
- Consistency of heating zone
- Abrasive test
- Fatigue bending resistance
- Pull test
- Shipping and transportation test
- Package evaluation using the burst test
- Visual inspection of medical packaging to determine integrity
- Package seal dye penetration test
- Functional validation for soft tissue indication

The following biocompatibility tests were performed:

- Elution Cytotoxicity and Hemolysis
- Implantation Test
- Intracutaneous toxicity
- Acute systemic injection

10. Electromagnetic and Electrical Testing

Testing was performed per the requirements of the following electromagnetic compatibility and electrical standards:

- IEC 60601-1:2006 + A1:2012, EN 60601-1:2006, ANSI/AAMI ES60601-1:2005 + C1:2009 + A2:2012 + A1:2010, and CAN/CSA-C22.2 No. 60601-1:2014: *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*

- IEC 60601-2-2:2009 + C1:2014 *Medical electrical equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*
- EN IEC 60601-2-18:2009 *Endoscopic equipment*;
  In conjunction with BS EN 60601-1:2006 +A11 and IEC 60601-1:2005 *Medical electrical equipment – Part 1 – General requirements for basic safety and essential performance*
- EN 55011:2007 *Limits and methods of measurements of electromagnetic disturbance characteristics of industrial, scientific and medical (ISM) radio-frequency equipment*
- EN 61000-3-2: 2006 *Electromagnetic compatibility (EMC*) -- Part 3-2: Limits - Limits for harmonic current emissions (equipment input current <= 16 A per phase)
- EN 61000-3-3:2006 *Electromagnetic compatibility (EMC*) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current <= 16 A per phase and not subject to conditional connection
- EN 61000-4-3:2006 *Electromagnetic compatibility (EMC)* – Part 4-3: Testing and measurement techniques – Radiated, radio-frequency, electromagnetic field immunity test
- EN 61000-4-8:1993 *Electromagnetic compatibility (EMC)* – Part 4-8: Testing and measurement techniques – Power frequency magnetic field immunity test

11. Substantial Equivalence Determination

The subject device, the Habib EUS RFA 6700 is substantially equivalent to legally marketed predicate devices, the Ace Monopolar Attachment and the LeVeen™Standard Needle Electrode System with respect to indications for use and technology characteristics. The Table below presents side by side comparisons for each major component of for each device:

Item	**Predicate Device** Ace Monopolar Attachment (K123061)	**Predicate Device** LeVeen™Standard Needle Electrode System (K140495)	**Subject Device** Habib EUS RFA 6700 (K150029)
Similarities			
Classification	II	II	II
Code of Federal Regulation	878.440	878.4400	878.4400
Prescription Medical Devices	Yes	Yes	Yes
Intended Use	The Ace Monopolar Attachement is intended to be used with the compatible ERBE Monopolar Disposable Electrosurgical Pencil for coagulation and cutting of soft tissue when used in conjunction with compatible ERBE Electrosurgical Generator (ESU) System.	The LeVeen™ Needle Electrode Family (which includes the LeVeen™ Standard Needle Electrode System and the LeVeen™ CoAccess™ Need Electrode System) is intended to be used in conjunction with the RF3000 Generator for the thermal coagulation necrosis of soft tissues, including partial or complete ablation of nonresectable liver	The Habib EUS RFA 6700 is indicated for coagulation and ablation of soft tissue when used in conjunction with compatible radio frequency generator.

		lesions.	
Active Accessory Configuration	Monopolar	Monopolar	Monopolar
Material of electrode tip	Stainless Steel	n/a	Stainless Steel
Safety Standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-2 ISO 10993-1 ISO10993-5 ISO 10993-10	IEC 60601-1 IEC 60601-2-2	IEC 60601-1 IEC 60601-2-2 IEC 60601-2-18 ISO 10993-1 ISO 10993-4 ISO 10993-5 ISO 10993-7 ISO 10993-10
Performance Tests	- Arcing Test - Charring Test - Thermal Spread Test - Dropping Test - Pulling Test	- Insulated Cannula Outer Diameter - Cannula Insulation Adhesion - Cannula Tensile - Cannula/Array Housing Handle Compression Strength	- Compatibility with endoscope needle - Trackability and pushability test - Consistency of heating zone test - Abrasion test - Fatigue bending resistance test - Pull Test - Shipping and Transportation Test - Burst Test (Package evaluation) - Package Seal Dye Penetration Test - Functional Validation for Soft Tissue Indication
Differences			
Sterilization	Gamma irradiation	Ethylene Oxide	Ethylene Oxide
Dimension	Shaft ϕ2.35mm	Shaft ϕ1.5-2.4mm	Shaft ϕ0.33mm
Delivery Mode	Electrosurgical pencil	Cannula (percutaneous)	Endoscopic needle, laparoscopes, ports, trocars
Rated Frequency	n/a	480 kHz	Up to 460 kHz

13. Conclusion

The Habib EUS RFA 6700 is substantially equivalent to the predicates Ace Monopolar Attachment (K123061) and LeVeen™Standard Needle Electrode System (K140495). The minor differences between the Habib EUS RFA 6700 and the predicates do not raise any new questions of safety or effectiveness. All product performance testing and electrical testing performance clearly demonstrate that the Habib EUS RFA 6700 is safe and effective.